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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,526	02/10/2000	Kuanghui Lu	CIBT-P01-058	1398

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/01/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/499,526

Applicant(s)

LU ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-33, 35-63, 65-67, 69-71 and 73-95 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85 and 87-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13, 15-33, 35-63, 65-67, 69-71 and 73-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-12,24-27,35-38,40-44,47-49,52,55,56,62,65-67,69-71,73-75,79-84 and 86.

Status of Application, Amendments and/or Claims

The amendment filed 24 March 2003 (Paper No. 32) and 26 June 2003 (Paper No. 34) have been entered in full. Claims 51 and 63 were cancelled. New claims 92-95 were added. Claims 13, 15-23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-95 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection of claims 30, 31 and 39 as set forth at page 2 of the previous Office Action (17 December 2002, Paper No. 30) is *withdrawn* in view of the amendment (24 March 2003, Paper No. 32).

The rejection of claims 13, 15-23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-91 under 35 USC 112, first paragraph, scope of enablement as set forth at pages 3-6 of the previous Office Action (17 December 2002, Paper No. 30) is *withdrawn in part* in view of the amendment (24 March 2003, Paper No. 32). Please see remaining scope of enablement issues below.

The rejection of claims 13, 15-23, 28-33, 39, 45, 46, 50, 51, 53, 54, 57-60, 63, 76-78 and 85 under 35 USC 112, second paragraph as set forth at page 6 of the previous Office Action (17 December 2002, Paper No. 30) is *withdrawn* in view of the amendment (24 March 2003, Paper No. 32).

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Specification

The disclosure is objected to because it states that human PYY protein is SEQ ID NO:2 which can be encoded by SEQ ID NO:1 (page 6, lines 1-10). SEQ ID NO:2 has 97 amino acid residues. However, the amendment entered 24 March 2003 (Paper No. 32) states that human PYY is SEQ ID NO:3 (page 21, lines 30-33). PYY is taught as a 36 amino acid residue (page 22, lines 20-24). The difference between SEQ ID NO:2 and SEQ ID NO:3 is unclear. Clarification is required.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 13, 15-23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 15-23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78 and 85 recite "a polypeptide encodable by" as opposed to "the polypeptide encoded by". "A" begs the question of which one. There are 6 possible open reading frames. "Encodable" begs the question of what conditions are required so that SEQ ID NO:1 does, in fact, encode the polypeptide. Lastly, "stringent conditions including a wash step of 0.2X SSC at 65 °C" allows for undefined lowering of stringency before termination of hybridization.

Claims 13, 15-20, 30, 31, 32, 53, 54, 87 and 92 are indefinite because of the recitation "altering the glucose-responsiveness". It is not clear *how* glucose-responsiveness is being altered (i.e. increase or decrease).

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Claims 33, 45, 46, 90, 91 and 95 are indefinite because of the recitation "maintaining or restoring a function of pancreatic β cells or islets". It is unclear *what* function is being maintained or restored.

Claims 87 and 92, 88 and 93, 89 and 94, 91 and 95 are indefinite because they recite the same method.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 13, 15-20, 21-23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78 and 85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for altering glucose metabolism in an animal identified as having a disease associated with abnormal glucose metabolism, comprising administering to the animal an amount of a composition comprising **PYY** wherein the amount is therapeutically effective to induce or enhance glucose responsiveness in the animal, thereby altering glucose metabolism in the animal,

a method for treating a disease associated with altered glucose metabolism, comprising administering to an animal identified as having a disease associated with altered glucose metabolism, an amount of a composition comprising **PYY**, wherein the amount is sufficient to increase glucose responsiveness of a pancreatic islet or cell in the animal,

does not reasonably provide enablement for:

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a method for altering glucose metabolism in an animal identified as having a disease associated with abnormal glucose metabolism, comprising administering to the animal an amount of a composition **including PYY agonist, wherein said PYY agonist comprises a polypeptide encodable by a nucleic acid that hybridizes under stringent conditions, including a wash step of 0.2X SSC at 65 °C, to SEQ ID NO:1**, wherein the amount is therapeutically effective to induce or enhance glucose responsiveness in the animal, thereby altering glucose metabolism in the animal

a method for treating a disease associated with altered glucose metabolism, comprising administering to an animal identified as having a disease associated with altered glucose metabolism, an amount of a composition comprising PYY agonist, **wherein said PYY agonist comprises a polypeptide encodable by a nucleic acid that hybridizes under stringent conditions, including a wash step of 0.2X SSC at 65 °C, to SEQ ID NO:1**, wherein the amount is sufficient to increase glucose responsiveness of a pancreatic islet or cell in the animal.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 3-6 of the previous Office Action (17 December 2002, Paper No. 30). Because the instant claims have been amended, the Examiner will only address Applicants' arguments regarding structural relationship to the PYY polypeptide.

Applicants state that the amended claims are explicitly directed to the use of PYY agonists comprising polypeptides which have a specific structural relationship to the

PYY polypeptide provided in the application. Applicants cite page 6, lines 1-9 and page 21, lines 30-33. Applicants' arguments have been fully considered but not deemed persuasive because the newly amended claims do not recite a specific structural relationship to the PYY polypeptide. As was stated above in the disclosure objection, the specification teaches two different SEQ ID NOs for human PYY protein (SEQ ID NO:2, page 6, lines 1-10 and SEQ ID NO:3, page 21, lines 30-33). Thus, it is not clear if SEQ ID NO:1 encodes human PYY. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
September 26, 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER